

REMARKS

Reconsideration of the pending application is respectfully requested in view of the following remarks.

Discussion of the Amendments

Claims 1, 29, and 52 are amended by moving the language in the “wherein” clause of each claim into an earlier portion thereof.

Discussion of the New Claims

Claims 1-64 and 68-70 were previously submitted and are currently under examination, with claims 1, 29 and 52 being amended and claims 65-67 previously having been canceled without prejudice. As the amendments to the application are fully supported by the application as filed, no new matter has been introduced into the application by way of these amendments.

Summary of the Office Action

Claims 1-17, 28-41 and 52-54 are provisionally rejected for alleged obviousness-type double patenting over claims 1-47 of copending U.S. Patent Application No. 10/434,776.

Claims 1 and 3-64 and 68-70 are rejected under 35 U.S.C. § 102(b) as allegedly unpatentable over U.S. Patent 6,399,087 (“Zhang et al.”).

Discussion of the Claim Rejections

With regard to the obviousness-type double patenting rejection, Applicants may file a terminal disclaimer addressing this rejection upon receipt of an indication of allowable subject matter.

With regard to the rejection under 35 U.S.C. § 102(b), Applicants respectfully traverse the anticipation rejection.

The Office Action alleges that Zhang et al. teaches compositions containing propofol with the other ingredients and in concentration ranges claimed in the current application. What is not alleged in the Office Action, however, is any disclosure or teaching in Zhang et al. relating to the use of any container for its compositions, let alone the use of a container which comprises a closure that is inert to propofol. In contrast to the assertion in the Office Action, the invention as described in independent claims 1, 29 and 52 provides a sterile

pharmaceutical composition of propofol in a container, and comprises both a container and a composition in the container. In claim 1, for example, the container includes a closure inert to propofol and the composition in the container comprises propofol and less than about 10% by weight solvent for propofol. One advantage provided by the claimed invention is a lessening of degradation and potency of propofol relative to prior art propofol packaged products. A container, and indeed one having a closure that is inert to propofol, is clearly a substantive limitation of the invention as claimed.

The Office Action asserts that Zhang et al. discloses each and every claim limitation. However, this argument ignores certain claim limitations relating to the container, and in particular the closure which is inert to propofol. In this regard, the Office Action argues that “how the propofol is stored is not relevant to the instant invention” because it does not modify the pharmaceutical composition. *See* Office Action, pages 5-6.

Applicants respectfully submit that the container which includes a closure inert to propofol is within the body of the claim, and must be considered as a substantive limitation. When the claims are considered in this manner, there is no question that the claims are patentable over Zhang et al.

Applicants note that it is not argued in the Office Action, nor could it be, that Zhang et al. discloses or teaches the claimed invention as a whole which includes both container and composition therein. More specifically, and in the case of illustrative claim 1, the invention provides a sterile pharmaceutical composition of propofol in a container, comprising a container which includes a closure inert to propofol and a composition in the container, the composition in the container comprising propofol and less than about 10% by weight solvent for propofol. Zhang et al. fails to disclose or teach the claimed combination of container and composition.

The Office Action relies on *Hoffer* in support of its argument that the “wherein” clause of claim 1 expresses merely the intended result of a process or method. The *Hoffer* court, however, was construing a “whereby” clause in a method claim (as opposed to a “wherein” clause), and the holding was restricted to those claims in which a “whereby” clause expresses the “intended result” of the process or method, but is not necessarily a part of the process or method itself. *See Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005). Thus, reliance on the *Hoffer* case is misplaced. This

being said, and to advance prosecution, Applicants have deleted the “wherein” clause and introduced the substance of that clause into an earlier portion of the claim.

As Zhang et al. fails to disclose or suggest the invention as recited in independent claims 1, 29 and 52, *e.g.*, a sterile pharmaceutical composition of propofol in a container, comprising a container which includes a closure inert to propofol and a composition in the container, the composition in the container comprising propofol and less than about 10% by weight solvent for propofol (claim 1), Applicants respectfully request that the rejection be withdrawn.

Summary of the Interview of April 28, 2009

A telephonic interview was conducted with Examiner Roy Teller on April 28, 2009, with Peter H. Domer and Christopher T. Griffith representing Applicants. Applicants appreciate the Examiner’s time in discussing the application.

During the interview, the constitution of the claims was discussed. At the conclusion of the interview, Examiner Teller agreed to enter and consider amendments to claims 1, 29 and 52 as set forth herein.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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